4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 314 and 601

[Docket No. FDA-2013-N-0500]

Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products; Public Meeting; Request for Comments; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is announcing a 1-day public meeting entitled "Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products." The purpose of the meeting is to provide a public forum for FDA to listen to comments on the proposed rule on "changes being effected" supplements that was published in the Federal Register of November 13, 2013, and alternatives offered to this proposed rule. FDA is also reopening the comment period for the proposed rule to receive submissions of additional written comments on the proposed rule as well as alternative proposals presented during the public meeting.

DATES: *Meeting*. The public meeting will be held on March 27, 2015, from 8 a.m. to 5 p.m. Registration to attend the meeting must be received by March 20, 2015. See the SUPPLEMENTARY INFORMATION section for information on how to register for the meeting.

Comments. The comment period for the proposed rule publilshed November 13, 2013 (78 FR 67985), is reopened. Submit either electronic or written comments regarding proposed alternatives to the proposed rule by April 27, 2015.

ADDRESSES: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave, Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

You may submit comments by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Docket No. FDA-2013-N-0500 for the proposed rule. All comments received may be posted without change to http://www.regulations.gov, including any personal information provided. For additional

information on submitting comments, see the "Comments" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ellen Molinaro, Center for Drug Evaluation and Research, Food and Drug Administration, Bldg. 51, rm. 6218, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-3601, FAX: 301-847-8440.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of November 13, 2013 (78 FR 67985), FDA proposed regulations to revise and clarify procedures for application holders of an approved drug or biological product to change the product labeling to reflect certain types of newly acquired safety-related information in advance of FDA's review of the change by submitting a changes being effected (CBE-0) supplement to FDA. The need to promptly communicate certain safety-related labeling changes based on newly acquired information is the basis for the "changes being effected" exception to the general requirement for FDA approval of revised labeling prior to distribution. The proposed rule, if finalized, would enable abbreviated new drug application (ANDA) holders for generic drugs to update product labeling promptly to reflect certain types of newly acquired safety-related information, irrespective of whether the revised labeling differs from that of the corresponding reference listed drug (RLD or brand drug) upon submission of a CBE-0 supplement to FDA. FDA's proposed revisions to its regulations to allow generic drug

manufacturers to update product labeling through CBE-0 supplements in the same manner as brand drug manufacturers are intended to improve communication of important, newly acquired drug safety information to health care professionals and the public. For further information about this and other proposed regulatory changes described in the proposed rule, see 78 FR 67985.

FDA received numerous comments on the proposed rule from a diverse group of stakeholders, including comments proposing alternative approaches to communicating newly acquired safety-related information in a multisource environment. In November 2014, FDA received a request from two trade associations for a listening meeting with FDA to present an alternative to the proposed regulatory changes described in the proposed rule that they described as intended to meet shared public health goals regarding multisource drugs (see Ref. 1). In December 2014, an explanatory statement accompanying the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235), supported a listening meeting between FDA and the regulated industries to consider alternative solutions to the proposed rule on safety labeling that will meet all public health goals relating to multisource drugs (see https://www.congress.gov/congressional-record/2014/12/11/house-section/article/H9307-1) (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the Federal Register).

In view of these requests and to promote transparency, FDA will hold a public meeting at which any stakeholders may present or comment on the proposed rule or any alternative proposals intended to improve communication of important newly acquired drug safety information to health care professionals and the public.

In addition, FDA is reopening the comment period for the proposed rule (78 FR 67985) until April 27, 2015, to receive submissions of additional written comments on the proposed rule as well as alternative proposals presented during the public meeting.

II. Registration and Requests for Oral Presentations

If you would like to attend the public meeting, please register for the meeting by email to CBESupplements.PublicMeeting@fda.hhs.gov by March 20, 2015. The e-mail should contain complete contact information for each attendee (including name, title, firm name or affiliation, address, email, telephone and fax numbers). Those without email access can register by contacting Ellen Molinaro (see FOR FURTHER INFORMATION CONTACT) by March 20, 2015. There is no fee to register for the meeting, and registration will be on a first-come, first-served basis. Early registration is recommended because seating is limited. Onsite registration on the day of the meeting also will be permitted on a space-available basis beginning at 7:30 a.m.

Individuals who wish to present at the public meeting must register on or before March 16, 2015, and provide complete contact information, including name, title, firm name or affiliation, address, email, telephone and fax numbers. You should provide a brief description of your presentation, and indicate the approximate desired length of your presentation, so that FDA can consider these in organizing the presentations. FDA will do its best to accommodate requests to speak and will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin. After reviewing the presentation requests, FDA will notify each participant before the meeting of the amount of time available and the approximate time their presentation is scheduled to begin. If time permits, individuals or organizations that did not register in advance may be granted the opportunity to make a presentation. An agenda will be posted on the FDA Web site at

http://www.fda.gov/Drugs/NewsEvents/ucm431265.htm prior to the meeting. Presenters are encouraged to submit a copy of their presentation and related written material to the docket (see "Comments") in advance of the public meeting.

If you need special accommodations because of a disability, please contact Ellen Molinaro (see FOR FURTHER INFORMATION CONTACT) at least 7 days in advance.

III. Streaming Webcast of the Public Meeting

This public meeting will also be Webcast. Information about how to view the live Webcast of this meeting will be posted on the FDA Web site at http://www.fda.gov/Drugs/NewsEvents/ucm431265.htm prior to the meeting.

IV. Comments

Interested persons may submit either electronic comments regarding proposed alternatives to the proposed rule to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

Electronic or written comments will be accepted after the public meeting until April 27, 2015.

V. Transcripts

Please be advised that as soon as possible after a transcript of the public meeting is available, it will be accessible at http://www.regulations.gov. It may be viewed at the Division of Dockets Management (see ADDRESSES). A transcript will also be available in either

hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

VI. Reference

The following reference has been placed on display in the Division of Dockets Management (see ADDRESSES), and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Letter dated November 14, 2014, from Mr. Neas (GPhA) and Mr. Castellani (PhRMA) to Dr. Hamburg (FDA) regarding request for listening meeting on Expedited Agency Review proposal.

Dated: February 11, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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